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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,555	11/06/2001	Alexander Vainstein	13687-003001/1242336	5237

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EXAMINER	
HELMER, GEORGIA L	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SMH

Office Action Summary	Application No.	Applicant(s)	
	09/992,555	VAINSTEIN ET AL.	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *16-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *22 April 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction/ Election

1. The Office acknowledges the timely receipt of Applicant's Election, dated 29 April 2004, electing Group I, claims 1-15, with traverse. Applicant traverses saying primarily that Group II, claims 16-19, are product-by-process claims and only cover products prepared by the method claim 1 of Group I. Applicant's traversal is unpersuasive. The process of making the product does not distinguish the products of the instant invention from the products made by PeiToa, et. al. Genetic transformation of Gypsophila paniculata by A. tumefaciens, Acta Agriculturae Shanghai, 1997, Vol 13, No. 4, pages 17-20. This restriction is made final.

Status of the Claims

2. Claims 1-19 are pending, claims 16-19 are withdrawn as being drawn to a nonelected invention, and claims 1-15 are examined in the instant action.

Information Disclosure Statement

3. Applicant's IDS filed 22 April 2003 is acknowledged and a signed copy included herewith.

Claim Rejections - 35 USC § 112 Enablement

4. Following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims drawn to a method of transforming a Gypsophila plant with a nucleic acid of interest, comprising pre-treating a Gypsophila plant with gibberellin (spraying with 4 ml of 1 mM GA3) 15 days prior to Agrobacterium tumefaciens cocultivation of stem explants in a cocultivation medium of MS medium supplemented with NAA (0.1mg/l), Benzylaminopurine (0.5 mg/l), and 100 µMolar acetosyringone, and Agrobacterium EHA105 for at least 3 days, where the cocultivation during at least the first 2 days is in the dark, and the cocultivation during at least the last day is in the light, after which 3 primary nodes were sectioned into ca. 3-mm slices and transferred to MS media supplemented with NAA (0.1mg/l), 3 mg/l/ TDZ , 300 mg/l carbenicillin, and 70 mg/l/l kanamycin (on the first selection cycle of 30 days); and with NAA (0.1mg/l), and 1 mg/l benzylaminopurine, 300 mg/l carbenicillin, and 100 mg/l/l kanamycin (on the second selection cycle of 20-40 days), then transferring the plants to MS medium containing NAA (0.1mg/l), and gibberillic acid (GA) 0.1 mg/l, 200 mg/l carbenicillin, and 70 mg/l/l kanamycin, is not enabled for the broad scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The breadth of the claims: The claims are drawn to a method of transforming a Gypsophila plant with a nucleic acid of interest comprising pre-treating the plant with a gibberellin, obtaining a plant segment from the treated plant, cocultivation said plant segment with an Agrobacterium vector comprising the nucleic acid of interest, selection and regenerating a transformed Gypsophila plant from a transformed plant segment, and to the method further comprising reselecting a plant segment from said transformed Gypsophila plant and regenerating a second transformed Gypsophila plant, where the gibberellin is GA3, GA1, GA4 or GA7, where the Agrobacterium is A. tumefaciens or A. rhizogenes, where the Agrobacterium is EHA105 or AGLO, where the plant is sprayed with the gibberellin, where the plant is treated with gibberellin 5 days or 15-30 days prior to taking the plant segment, where the plant segment is a stem explant, a leaf explant, or a seedling, where the stem explant comprises at least 3 primary nodes, where the cocultivation is for at least 3 days, and at least the

first 2 days are in the dark and at least the last day is in the light. The claims are broadly drawn to all nucleic acids, pretreatment of the plant with gibberellin for any time duration with any concentration of gibberellin, where the gibberellin includes GA3, GA1, GA4 and GA7, to any plant segment, including a stem, seedling, leaf, root, flower, or primary nodes of the explant, to the use of any Agrobacterium tumefaciens or rhizogenes including EHA105 and AGLO, to any and unspecified cocultivation conditions, medium, duration and light conditions.

Guidance: Applicant describes a method of transforming a Gypsophila plant with a nucleic acid of interest, comprising pre-treating a Gypsophila plant with GA3 gibberellin 15 days prior to Agrobacterium tumefaciens cocultivation of stem explants in a cocultivation medium of MS medium supplemented with NAA (0.1mg/l), Benzylaminopurine (0.5 mg/l), and 100 µMolar acetosyringone, and Agrobacterium EHA105 for at least 3 days, where the cocultivation during at least the first 2 days is in the dark, and the cocultivation during at least the last day is in the light, after which 3 primary nodes were sectioned into ca. 3-mm slices and transferred to MS media supplemented with NAA (0.1mg/l), 3 mg/l/ TDZ , 300 mg/l carbenicillin, and 70 mg/l/l kanamycin (on the first selection cycle of 30 days); and with NAA (0.1mg/l), and 1 mg/l benzylaminopurine, 300 mg/l carbenicillin, and 100 mg/l/l kanamycin (on the second selection cycle of 20-40 days), then transferring the plants to MS medium containing NAA (0.1mg/l), and gibberillic acid (GA) 0.1 mg/l, 200 mg/l carbenicillin, and 70 mg/l/l kanamycin (specification, p. 3 line 12 bridging to p. 4 line 13, and page 7 through page 10 line 21).

The state of the art and the predictability of the art: Plant transformation procedures employing plant tissue culture protocols are unpredictable. "Plant transformation is an art because of the unique culture conditions required for each crop species. To accommodate a genotype or species that has not been manipulated in culture previously, one must either adapt an established protocol or create a new one.",(Hansen et. al., 1999, Trends in plant Science, vol 4, pages 226-231, see page 230). Therefore it is unpredictable that a detailed and specific transformation protocol and methods which work for Gypsophila would function as desired for a protocol without those specific and detailed steps. Gypsophila is a plant which is recalcitrant to transformation (specification, p. 3, lines 17-18).

The regeneration of plants from explants such as stems is unpredictable, and explant selection is critical for successful plant regeneration. See Tisserat, in Plant Cell Culture, ed R.A. Dixon, 1985, IRL Press, Oxford, pages 79-105, especially page 80, Table 1, page 82, and Table 4, pages 85-90.

Experimentation required: Undue experimentation would be required to determine what kind of pre-treatment of the Gypsophila with gibberellin would function as desired. Pretreatment could be by various methods (spraying, dunking, sprinkling dry powder, adding to the soil as supplement) with any gibberellin (GA3, GA1, GA4, GA7 or other of the 50+ gibberellins known) and in any quantity (from virtually none to an infinite amount) for what duration (a single treatment or multiple treatment, or ongoing treatment, or episodic treatment) at what timeframe relative to the Agrobacterium cultivation (immediately before, an hour before, a day before, a week before, 2 weeks, a month before). Then the

specific plant part would have to be chosen: Many explants are known (stems, roots, flowers, leaves and nodes) from any age of plant from seedlings to senescent or AARP plants. Once these parameters were determined, the Agrobacterium cocultivation protocol which functions as desired would need to determined (what Agrobacterium, tumefaciens or rhizogenes, which strain of a very large number available) in what cocultivation medium (what if any hormones are added, at what concentration, are vir inducers used, if yes, which one(s)) for what duration of treatment (a minute to a number of days) under what light/dark conditions.

Therefore, given the breadth of the claims; the lack of guidance; the unpredictability in the art; and the nature of the invention, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

Remarks

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax

phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer
Patent Examiner
Art Unit 1638
July 3, 2004

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